UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

ENTERED

July 21, 2003

OFFICE OF
AIR AND RADIATION

Dr. Inés Triay, Manager
U.S. Department of Energy
Carlsbad Field Office
P.O. Box 3090
Carlsbad, NM 88220

Dear Dr. Triay:

During June 17-19, 2003, the U.S. Environmental Protection Agency (EPA or Agency) conducted an inspection of a Department of Energy (DOE) audit of the Hanford Site's Quality Assurance (QA) Program for the Waste Isolation Pilot Plant (WIPP). The Hanford QA Program provides on-site surveillance of waste characterization activities for transuranic (TRU) waste to be disposed at WIPP. The investigation of the activities selected for the EPA inspection and DOE audit samples showed that since approximately January 1, 2003, Hanford has not properly maintained the independence of its QA organization from cost and schedule considerations. In addition, organizational changes at Hanford have eroded the authority of the site's QA organization. As a consequence, EPA's inspection resulted in a finding regarding Element 1 ("Organization") of the National Quality Assurance (NQA) Standards. TRU wastes that were characterized after January 1, 2003, shall not be shipped to the WIPP until the EPA verifies corrective actions at the Hanford site. TRU waste that was characterized before that date shall require DOE QA approval prior to shipment. EPA will conduct a follow-up inspection in late July to verify completion of corrective actions. Based on the results of the follow-up inspection, the EPA will define the controls needed for those drums characterized after January 1. An enclosed report documents the results of our inspection.

The Agency's finding regarding Hanford's QA program is in concurrence with the corrective action report (CAR) issued by DOE's Carlsbad Field Office (CBFO) QA Organization requiring immediate remedial action by Hanford Site personnel. We agree with CBFO QA's assessment of both the nature and the timing of the breakdown in Hanford's QA Program. The DOE and EPA communicated during and after the inspection to discuss this critical finding of non-conformance regarding the independence and authority of the Hanford QA program. In a June 24, 2003, letter, EPA established actions necessary to: (1) verify Hanford's implementation of corrective actions; (2) control continuing waste deliveries; and (3) assess the magnitude of the finding, including its possible effects on the WIPP. A copy of this letter is provided as Attachment 2 of the enclosed report. We have reviewed WIPP shipments of Hanford on June 24, June 26, July 1, and July 8, and confirmed that QA was properly applied to these shipments. Furthermore, DOE has documented that there is no waste already emplaced in the

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WIPP that was characterized at Hanford after January 1, 2003 (the estimated date of the breakdown in the QA program). DOE must continue to review Hanford shipments, and notify EPA of the results—as specified in our June 24 letter—until the QA program finding has been adequately resolved.

To evaluate whether the finding is being addressed, EPA will inspect the Hanford QA program within 30 days of issuance of this letter. We will examine what corrective actions the Hanford TRU Program has taken or has planned to address in the CAR and whether the Hanford QA program staff has adequate independence, authority, and resources available to verify quality of Hanford's approved waste characterization activities. Based on the inspection, EPA will determine whether additional QA inspections or other oversight actions may be necessary.

Finally, we would like to recognize the professionalism of the CBFO QA Program. During the inspection, CBFO QA Program staff demonstrated a thorough understanding of the NQA standards applicable at Hanford. Their open communication and prompt imposition of additional oversight measures were key factors in providing confidence to EPA that the issues with Hanford QA were assessed objectively, and that they are likely to be aggressively addressed to ensure that waste destined for WIPP is adequately characterized and meets EPA's requirements.

This report will be made available to the public through the Agency's public dockets. Please contact Betsy Forinash at (202) 564-9310 or Mike Eagle at (202) 564-9376 if you have questions regarding the report.

Sincerely,

Bonnie Gitto for

Frank Marcinowski
Director, Radiation Protection Division

Enclosure

cc: Ava Holland (CBFO) (w/enclosure)
Matthew Silva (EEG) (w/enclosure)
Steve Zappe (NMED) (w/enclosure)

DOCKET NO: II-A1-46

EPA INSPECTION OF THE DOE HANFORD SITE QUALITY ASSURANCE PROGRAM FOR THE WASTE ISOLATION PILOT PLANT

June 17-19, 2003

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Center for Federal Regulations
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

July 2003

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1.0 EXECUTIVE SUMMARY

During June 17-19, 2003, the U.S. Environmental Protection Agency (EPA or Agency) conducted an inspection of a Department of Energy (DOE) audit of the Hanford Site's Quality Assurance (QA) Program for the Waste Isolation Pilot Plant (WIPP). The investigation of the activities selected for the EPA inspection and DOE audit samples showed that since January 1, 2003, Hanford has not properly maintained the authority and independence of its QA organization. Transuranic (TRU) wastes that were characterized after January 1, 2003, shall not be shipped to the WIPP until the EPA verifies completion of corrective actions. TRU waste that was characterized before that date shall require DOE QA approval prior to shipment. EPA will conduct a follow-up inspection in late July to verify completion of corrective actions. Based on the results of the follow-up inspection, the EPA will define the controls needed for those drums characterized after January 1. In addition, DOE has documented that there is no waste already emplaced in the WIPP that was characterized at Hanford after January 1.

Hanford, located along the Columbia River near Richland, Washington, is a 560-square-mile area managed by DOE. Transuranic (TRU) wastes at Hanford are destined for disposal at the WIPP, the geologic repository for the disposal of the nation's TRU wastes. Hanford's responsibilities include the proper execution of a QA Program to oversee the characterization of TRU waste.

The EPA inspectors performed the following activities:

(1) Verified that DOE conducted its audit properly, and
(2) Participated in the DOE audit to evaluate its findings and conclusions.

The EPA and DOE found one critical finding of non-conformance. Hanford's QA Organization no longer has sufficient independence from cost and schedule considerations to properly oversee the characterization of TRU waste. This problem seemed to appear after January 1, 2003 and does not warrant a suspension of shipments of waste that were characterized before that date.

The DOE and EPA communicated during and after the audit to address this critical finding. Two letters were issued to establish preliminary plans to: (1) verify Hanford's implementation of corrective actions, (2) control further waste shipments; and (3) assess the effects of the non-conformance on the WIPP. The letters, one from DOE and one from EPA, are provided as Attachment 2 of this report.

The EPA inspectors agree with the DOE audit team's findings of non-conformance and conclusions regarding Hanford's QA program. Attachment 3 provides a summary of the DOE audit results. This report will be made available to the public through the Agency's public dockets.

2.0 BACKGROUND

2.1 Regulatory Background

In January 2000, the U.S. Environmental Protection Agency (EPA or Agency) determined the Hanford Site's compliance with requirements for site-specific Quality Assurance (QA) programs. EPA reviewed and checked implementation of Hanford's QA Plan, as required under 40 CFR §194.8(a)(1) &(2). In accordance with 40 CFR §194.8(a)(3), EPA provided its written decision finding that the Hanford QA Program complied with the requisite QA requirements for a transuranic (TRU) waste generator site.

Subsequent to the determination of compliance, EPA conducted four inspections in accordance with §194.8(a)(4) to confirm continued compliance of the Hanford QA program. This report documents the Agency's fourth inspection to confirm continued compliance of the Hanford QA program.

Under 40 CFR §194.22(a)(1), EPA requires the Department of Energy (DOE) to adhere to a QA program that establishes and implements the requirements of the following Nuclear Quality Assurance (NQA) standards: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The EPA verified that DOE established these requirements in the Quality Assurance Program Document (QAPD) included in the Compliance Certification Application (CCA) for the Waste Isolation Pilot Plant (WIPP). The QAPD is the documented QA Plan for the WIPP project, as a whole, to establish the NQA standards. The QAPD is issued by the QA Organization of DOE's Carlsbad Field Office (CBFO), which has the authority to audit all other organizations associated with TRU waste disposal at the WIPP to ensure that their lower-tier QA programs establish and implement the applicable requirements of the QAPD. The DOE generator sites, which will characterize TRU waste for disposal in the WIPP, must prepare site-specific QA Plans that establish the applicable QAPD requirements.

The EPA annually audits DOE's QA program at CBFO (reference EPA Air Docket No. A-93-02, Document Nos. II-A-43 and IV-A-4, and EPA Air Docket No. A-98-49, Document No. II-A-1-4) and has found that DOE properly adheres to a QA program that implements the NQA standards. EPA determined in its WIPP Certification Decision (43 FR 27345) that the CBFO QAPD establishes the NQA requirements and that the DOE's QA organization can properly perform audit activities to internally check the QA programs of the waste generator sites.

The Agency's inspection of CBFO Audit A-03-14 was performed under the authority of 40 CFR §194.8(a)(4), which addresses continued compliance of generator sites QA programs. During an EPA audit, the Agency assumes all responsibilities associated with assessing a QA program. During an EPA inspection, the Agency performs some oversight of DOE's checks of a QA program at TRU waste generator sites. Further, EPA performs some independent assessment, or audit-type, activities during the course of inspecting a DOE audit. The table below presents a summary of EPA inspection and audit activities conducted of the Hanford's QA Program to date.

Summary of EPA Inspections and Audit Activities at the Hanford Site		
Activity	**Date**	**Purpose**
Inspection	January 24-28, 2000	Inspection and independent assessment of initial CBFO Certification Audit A-00-05 of QA program for conformance with 40 CFR 194.8(a)
Inspection	January 16, 2001	Inspection and independent assessment of CBFO Surveillance S-01-04 for maintenance of QA program for conformance with 40 CFR 194.8(a)
Inspection	June 12-15, 2001	Inspection of CBFO Audit A-01-03 and A-01-16 of QA program maintenance.
Inspection	June 25-27, 2002	Inspection of CBFO Audit A-02-23 of QA program maintenance.
Inspection	June 24-26, 2003	Inspection of CBFO Audit A-03-14 of QA program maintenance.

2.2 Hanford Site Background

Hanford, located along the Columbia River near Richland, Washington, is a 560-square-mile area managed by the DOE. Hanford was established in secrecy during World War II to produce plutonium for the United States' nuclear weapons program. Peak production years were reached in the 1960s when eight reactors were operating at Hanford. All weapons material production was halted in the late 1980s. Hanford is now engaged in the world's largest environmental cleanup project. TRU wastes generated at Hanford during the production years and during environmental cleanup are destined for disposal at the WIPP, the geologic repository for the

disposal of the nation's TRU wastes. Hanford serves as an interim storage facility for defense-generated TRU-contaminated waste. Hanford is also responsible for the waste characterization (WC) of TRU-contaminated waste that will be shipped to the WIPP. In addition, Hanford is responsible for executing a QA Program to oversee its TRU WC activities.

3.0 PURPOSE AND SCOPE

Section 194.22(a)(1) requires that the WIPP establish and implement the requirements of: 1) ASME NQA-1-1989 edition; 2) ASME NQA-2a-1990 Addenda, Part 2.7, to ASME NQA-2-1989 edition; and 3) ASME NQA-3-1989 edition (excluding Section 2.1(b) and (c) and Section 17.1). The purpose of this EPA audit was to confirm the continued compliance of the Hanford's QA Program with the above requirements.

Section 194.22(a)(2) requires that WIPP properly execute a QA Program for all items and activities that are important to the containment of TRU-waste at the WIPP. The scope of this EPA audit was the Hanford's QA Program's oversight of items and activities that are important to the containment of TRU waste at the WIPP. Currently, Hanford characterizes contact-handled (CH) TRU-waste that is destined for disposal at the WIPP, an activity listed under 194.22(a)(2)(i). Therefore, the scope of the EPA audit was limited to the QA Program's oversight of the WC activities. Section 194.22(a)(2) reads as follows:

> (2) Any compliance application shall include information which demonstrates that the quality assurance program required pursuant to paragraph (a)(1) of this section has been established and executed for:
>
> (i) Waste characterization activities and assumptions;
> (ii) Environmental monitoring, monitoring of the performance of the disposal system, and sampling and analysis activities;
> (iii) Field measurements of geologic factors, ground water, meteorologic, and topographic characteristics;
> (iv) Computations, computer codes, models and methods used to demonstrate compliance with the disposal regulations in accordance with the provisions of this part;
> (v) Procedures for implementation of expert judgment elicitation used to support applications for certification or re-certification of compliance;
> (vi) Design of the disposal system and actions taken to ensure compliance with design specifications;
> (vii) The collection of data and information used to support compliance application(s); and
> (viii) Other systems, structures, components, and activities important to the containment of waste in the disposal system.

4.0 DEFINITIONS

Finding: A determination that a specific item or activity does not meet a requirement under applicable elements of the NQA standards. A finding requires a response.

Concern: A judgment that a finding may occur in the future, and depending on the magnitude of the issue, may or may not require a response.

Quality: The reliability or worth of a specific item or activity that is important to the containment of TRU-waste at the WIPP. *Quality Achievement* is the responsibility of organizations that directly produce such an item or perform such an activity. *Quality Verification* is the responsibility of QA organizations that do not produce such items or perform such activities. For example, a failure to achieve quality is not the responsibility of the QA organization that verifies quality achievement.

5.0 INSPECTION TEAM AND PARTICIPANTS

The EPA inspection team consisted of the following personnel:

Team Member	Position	Affiliation
Mike Eagle	Lead Inspector	EPA's Office of Radiation and Indoor Air
Rajani Joglekar	Inspector	EPA's Office of Radiation and Indoor Air
Ed Feltcorn	Inspector	EPA's Office of Radiation and Indoor Air
Robert Thielke	Inspector	Trinity Engineering Associates

Numerous DOE and Hanford personnel participated in the inspection. CBFO was supported by the CBFO Technical Assistance Contractor (CTAC). Ms. Ava Holland, CBFO's QA Manager, served as the EPA inspector's point of contact with DOE and Hanford. Dennis Miehl, DOE CBFO's QA Specialist also partipated in the QA inspection activities at Hanford. The CBFO audit report will provide a list of participants in their audit.

6.0 PERFORMANCE OF THE INSPECTION

The EPA Inspector performed the following activities:

(1) reviewed Hanford's QA Plan,
(2) reviewed compliance with the NQA *Organization* element, and
(3) observed DOE's conduct of audit A-03-14.

6.1 Hanford's QA Plan

The EPA reviewed Hanford's QA Plan, contained in Section 5.0 of the *Hanford Site Transuranic Waste Certification Plan*, HNF-2600. The EPA identified no findings related to this review.

6.2 Organization

The EPA interviewed Jim Maupin, Hanford's Site Quality Assurance Officer (SQAO), Stewart Huggins, other Hanford QA staff, and other Hanford personnel. Based on the interviews, EPA finds that Hanford's QA Organization has sufficient qualifications and access to work areas to perform their verification functions properly. However, EPA finds that Hanford's QA Organization no longer has sufficient resources, independence, and authority to verify quality assurance related to the CH TRU waste characterization activities commensurate with the expedited production schedule. (See section 7.1 of this report for a detailed description of the EPA finding.)

6.3 Conduct of DOE Audit

The EPA inspected CBFO Audit A-03-14 for compliance with the requirements of NQA-1 Element 18; "Audits." DOE's audit of Hanford was well-planned and well-conducted to verify the proper execution of Hanford's WC and QA Programs. The CBFO auditors developed and completed checklists for activities associated with both the WC and QA Programs. The checklists were developed based on the requirements of the top-tier document, the CAO QAPD, and procedures for the characterization of TRU waste. The complete audit report for Audits A-03-14 has not been distributed; therefore, the EPA inspection team cannot verify if the audit results are documented, reported to, and reviewed by responsible management. However, DOE did provide the executive summary of the audit reports for review; and this summary is presented in Attachment 3. The Agency concluded that the reporting requirement will be met based on previous EPA inspections and audits of CBFO, reviews of other CBFO audit reports, and the information provided in the audit summary. EPA may review the audit report during future audits to verify that this requirement was satisfied. The EPA determined that CBFO's auditing team consisted of qualified auditors who are independent of the Hanford QA activities. EPA reviewed documents contained in *Audit Team Qualifications* provided by CBFO QA. Mr. Pete Rodriguez, CTAC, served as the lead auditor for Audits A-03-14.

6.4 General Inspection Results

Based on the results of the Agency's inspection, EPA determined that Hanford has not properly maintained its QA program related to NQA Element 1: Organization. Transuranic wastes that were characterized after January 1, 2003, shall not be shipped to the WIPP until the EPA verifies completion of corrective actions. Transuranic wastes that were characterized before that date shall require DOE QA approval prior to shipment. EPA will conduct a follow-up inspection in late July to verify completion of corrective actions. In addition, DOE has documented that there is no waste already emplaced in the WIPP that was characterized at Hanford after January 1, 2003 (the estimated date of the breakdown in the QA program).

7.0 SUMMARY OF FINDINGS

The EPA had one finding that was incorporated into the DOE audit.

7.1 Finding regarding Organization

40 CFR Part 194.22 requires DOE to execute a QA program for items and activities that are important to the containment of transuranic waste within the WIPP, including the TRU WC activities at the Hanford Site. Hanford's QA program must be in accordance with the Nuclear Quality Assurance (NQA) standards developed by The American Society of Mechanical Engineers. The *Organization* element of the NQA standards requires that "*...organizations responsible for...verifying that activities affecting quality have been correctly performed...shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.*" However, personnel interviews during the audit indicated that from January 1, 2003, Hanford's QA Organization did not have sufficient independence from cost and schedule considerations.

The EPA finds that Hanford's QA resources did not keep pace with increasing activities in CH TRU waste characterization. The quantity of field inspections performed by Hanford QA staff is now insufficient to properly verify the quality of WC activities. The QA staff is working overtime just to keep-up with reviews of QA records. The EPA finds that organizational changes have eroded too much of the authority of the QA Organization. Access to upper management has decreased since a reorganization that occurred around Fall 2002, and weekly meetings between the SQAO and senior management no longer take place. The SQAO does not seem to have the same level of authority as seen during the previous EPA inspection. The SQAO is now not a direct employee of Fluor Hanford. Operational groups now challenge the independence of the QA Organization. The Plutonium Finishing Plant operational groups exert pressure on the QA Organization through new management that is insufficiently aware of EPA requirements. The QA Organization generally resisted these pressures successfully in most instances.

The DOE and EPA communicated during and after the audit to address this finding. Two letters were issued to mainly to establish preliminary plans to: (1) verify implementation of corrective actions by Hanford; (2) control further waste shipments; and (3) assess the effects of the non-confomance on the WIPP. The letters, one from DOE and one from EPA, are provided as Attachement 2 of this report.

ATTACHMENT 1

ELEMENT 18 CHECKLIST
EPA'S EVALUATION OF DOE'S AUDIT

NQA-1 CHECKLIST
CBFO Audits A-03-14
June 17-19, 2003

ELEMENT: 18 TITLE: Audits INSPECTOR: Mike Eagle

Does the reference document adequately define, describe, address, or satisfy the following:	Yes	No	Applicable Procedure & Para.
Basic Requirements			
1. Are planned and scheduled audits performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness?	X		CBFO Audit Schedule CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras. 3.1.C
2. Are audits performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited?	X		Audit Plan A-03-14 Audit Checklists for A-03-14 CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras. 3.2.2.7.A and 3.2.2.3.A
3. Are audit results documented and reported to and reviewed by responsible management? Is follow-up action taken where indicated?	X		Concerns reported daily to Hanford management during the audit. Corrective action taken during audit where possible. The audit team identified those concerns that would require formal corrective action and issuance of the

			CBFO CAR CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras. 1.3.3.7, 3.2.2.8 and 3.2.2.9
Supplementary Requirement (18S-1)			
1. Are internal or external quality assurance audits scheduled to provide coverage and coordination with ongoing quality assurance program activities?	X		Audit Plan A-03-14 This audit was the annual recertification audit required by the EPA Compliance Decision and the Compliance Certification Application CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.1
2. Are audit plans developed and documented for each audit?	X		Audit Plan A-03-14 CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.2
3. Does the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit? In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.	X		Copys of CBFO's Auditor Qualification records for the Audit Team Leader, Auditors, and Technical Specialists CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.3

4. Is the audit team identified prior to the beginning of each audit, with one individual appointed lead auditor?	X		Audit Plan A-03-14 CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras.3.2.2.3
5. Are audits performed in accordance with written procedures or checklists?	X		Checklist for each procedure reviewed during CBFO Audits A-03-14. CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.7A
6. Are the elements that have been selected for audits evaluated against specified requirements?	X		The audit plan for A-03-14 required that the audit be based on: CBFO Quality Assurance Program Document (QAPD), DOE-CBFO-94-1012 Contact-Handled Waste Acceptance Criteria (CH-WAC) for the Waste Isolation Pilot Plant, DOE/WIPP-02-3122 Hanford Quality Assurance Project Plan (QAPjP) for the Transuranic Waste Certification Program, HNF-2599 Hanford Site Transuranic Waste Certification Plan (includes TRAMPAC), HNF-2600

			Related Hanford technical and quality assurance implementing procedures Checklist for each procedure reviewed during CBFO Audits A-03-14. CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.7B
7. Are audits results documented by auditing personnel and reviewed by management having responsibility for the area audited?	X		CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.7C
8. Is the audit report signed by the lead auditor prior to issuance?	X		CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.8
9. Does the audit report include: description of the audit scope; identification of the auditors; identification of persons contacted during audit activities; summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; and description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization?	X		CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras. 3.2.2.8 A
10. Does the management of the audited organization or activity investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence), and notify the appropriate organization in writing of action taken or planned?	X		CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Paras. 1.3.1 A through C, and 3.2.4.9
11. Is follow-up action taken to verify that corrective action is accomplished as scheduled?	X		CBFO QAPD, DOE/CBFO-94-

12. Do audit records include audit plans, audit reports, written replies, and the record of completion of corrective action?	X		1012, Rev. 5, Paras. 1.3.3.7 and 3.2.2.9 Audit working papers for CBFO Audits A-03-14 CBFO QAPD, DOE/CBFO-94-1012, Rev. 5, Para. 3.2.2.10

ATTACHMENT 2

COMMUNICATIONS BETWEEN EPA AND DOE
2 LETTERS

ATTACHMENT 3

DOE'S AUDIT SUMMARY

PROVIDED TO EPA BY DOE
ON JUNE 27, 2003

SUMMARY OF DOE'S AUDIT RESULTS

Carlsbad Field Office (CBFO) Audit A-03-14 was conducted to re-evaluate the adequacy, implementation, and effectiveness of the Hanford Site transuranic (TRU) waste characterization, transportation, and certification activities. The audit was conducted to evaluate retrievably stored and newly generated debris (S-5000), contacted-handled waste at the Waste Receiving and Processing (WRAP) facility. The audit also assessed newly generated debris and homogeneous solids (S-3000 and S-5000), characterized at the Plutonium Finishing Plant (PFP) and WRAP and T-Plant, as applicable. In addition, the audit evaluated the procedure and processes for assay and packaging of waste at the PFP.

The audit was conducted at the Hanford Site during the week of June 16-20, 2003. The audit team concluded that the Hanford technical and quality assurance (QA) procedures continue to be adequate relative to the flow down of requirements from the CBFO Quality Assurance Program Document (QAPD), the Waste Analysis Plan (WAP) of the Hazardous Waste Facility Permit (HWFP), Contact Handled - Waste Acceptance Criteria (CH-WAC), the TRUPACT-II Safety Analysis Report, TRAMPAC, and the TRUPACT-II Certificate of Compliance, NRC-Docket 71-9218.

The audit team has concluded that the Hanford QA program continues to satisfactorily meet the requirements of the QAPD, WAP, CH-WAC, and TRAMPAC. The audit team also concluded that the QA program is being satisfactorily implemented and, except for the areas noted in this report, that the Hanford technical processes evaluated are satisfactorily implemented and effective.

The audit team identified four conditions adverse to quality that resulted in the issuance of four CBFO corrective action reports (CARs), which require corrective action in the areas of Organization/Assessment, AK, Project Level V&V/(RTR & VE), and transportation. Six isolated deficiencies requiring only remedial corrective actions were corrected during the audit (CDA). Three Observations were identified, and six recommendations are being offered for Hanford management's consideration.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
AIR AND RADIATION

June 24, 2003

Dr. Inés Triay, Manager
U.S. Department of Energy
Carlsbad Field Office
P.O. Box 3090
Carlsbad, NM 88220

Dear Dr. Triay:

On June 17-19, 2003, the U.S. Environmental Protection Agency (EPA) conducted an inspection of a Carlsbad Field Office (CBFO) audit of the Hanford Site's quality assurance (QA) program for the WIPP. The EPA inspection team concurs with a CBFO concern that identified a breakdown in the Hanford QA program. (See attached letter from Ava Holland to Mike Eagle dated June 19, 2003.)

40 CFR Part 194.22 requires DOE to execute a QA program for items and activities that are important to the containment of transuranic waste within the WIPP, including the transuranic waste characterization activities at the Hanford Site. Hanford's QA program must be in accordance with the Nuclear Quality Assurance (NQA) standards developed by The American Society of Mechanical Engineers. The *Organization* element of the NQA standards requires that "*...organizations responsible for...verifying that activities affecting quality have been correctly performed...shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.*" However, personnel interviews during the audit indicated that Hanford's QA Organization did not have sufficient independence from cost and schedule considerations. In addition, resources for the QA Organization appeared insufficient for a growing rate of waste characterization activities. An EPA inspection report will follow this letter to further document this issue.

With EPA participation, the DOE QA Manager reviewed documentation of QA activities related to the shipment scheduled for June 19, 2003. The EPA inspectors concurred that the concerns did not have an adverse effect on the QA activities performed in preparation for the shipment. Therefore, the EPA approved that the shipment could continue.

Until corrective actions from the inspection can be completed and verified, all shipments of waste from Hanford to WIPP must be reviewed by CBFO QA, as described in Ms. Holland's letter, to confirm that QA has been adequately applied. The EPA must be notified of the results of CBFO's review for each shipment prior to its departure from Hanford. Drums shall not be approved for shipment until verification of satisfactory completion of corrective actions related to those drums. The EPA will conduct follow-up inspections to verify implementation of corrective actions at the Hanford site.

The EPA concurs with the CBFO QA Manager's assessment that the breakdown occurred on or around the time of January 1, 2003, and that it may have had an adverse effect on the QA of drums processed after January 2003. The EPA requires that CBFO QA identify drums characterized after January 1, 2003, and already emplaced in the WIPP. CBFO QA must conduct reviews—equivalent to those being conducted for current shipments from Hanford—to determine if the QA was adequate for those shipments, and provide the results of such reviews to EPA. DOE should provide EPA, within one week of receipt of this letter, a summary of the shipments that were sent and a schedule for completing these reviews.

This letter will be placed in EPA Air Docket No. A-98-49. Please contact Betsy Forinash at (202) 564-9233 if you have questions.

Sincerely,

Frank Marcinowski, Director
Radiation Protection Division

Enclosure

cc: Matthew Silva (EEG)
Ava Holland (CBFO)
Steve Zappe (NMED)
Mark French (DOE)
Lynn Smith (DOE)

Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221

June 19, 2003

Mr. Mike Eagle
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Eagle:

I have reviewed the documentation of Quality Assurance (QA) activities related to the payload scheduled for shipment from Hanford Site to WIPP on June 19, 2003. I have verified to my satisfaction that the condition identified during CBFO Audit 03-14 as concern number one has not had an adverse effect on the QA activities performed in preparation for the shipment.

This concern number one identifies a break down in the Hanford TRU Waste QA program in the NQA-1 elements of organization and assessments. The breakdown occurred on or around the time of January 1, 2003. The evidence I have evaluated clearly shows that this breakdown in administrative functions of the QA program did not affect these particular drums. In the evidence I reviewed there were documents indicating that deficiencies associated with these drums had been identified, documented and corrected.

At the same time as my review of these particular drums, my Audit Team also verified the adequacy, implementation and effectiveness of the characterization processes performed on these drums. Based on this review I have concluded that except for the above identified QA elements, the remainder of the QA program was implemented and effective. I do not have a similar satisfaction that the breakdown in these administrative elements did not have an adverse affect on the QA of drums processed after January 2003. Therefore, an accelerated significant corrective action report will be issued to document and track necessary corrective actions until satisfactory closure of the identified condition adverse to quality.

In the interim period that is necessary for corrective action to be performed and verified, I will perform the same review on upcoming shipments. Drums characterized during or after January 2003 will not be approved for shipment until verification of satisfactory completion of corrective actions. This review and approval process will be performed in addition to the normal shipment review and approval process required by the site's certification authority.

Sincerely,

Ava L. Holland
Quality Assurance Manager

CBFO:QA:ALH:JDR:03-1547:UFC:2300

cc:
I. Triay, CBFO
K. Watson, CBFO
B. Forinash, EPA
M. French, RL
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